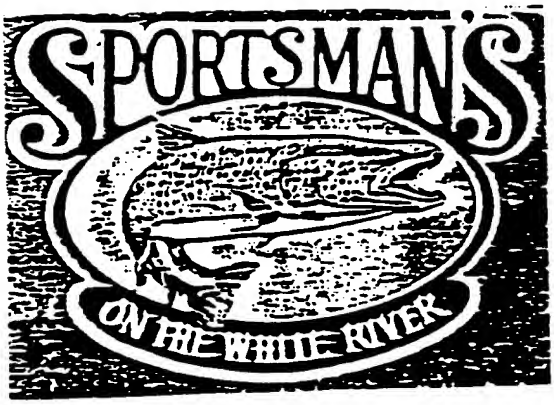

Court of Appeals, Federal Circuit

U.S. v. Telectronics Inc.

Nos. 87-1445, -1446

Decided September 22, 1988

PATENTS

1. Patent construction — Claims — Broad or narrow (§125.1303)

Federal district court erred in interpreting claim for bone growth stimulator device by limiting claim to non-implanted anodes and excluding anodes implanted adjacent to bone and by basing interpretation on claim language which cautions against formation of "fibrous tissue" around anode, since such language is not determinative of anode placement.

2. Patent construction — Claims — Broad or narrow (§125.1303)

Doctrine of claim differentiation presumes difference in meaning and scope when different words or phrases are used in separate claims, and thus federal district court erroneously construed claim of bone healing invention so that its limitations are same as dependent claim.

3. Infringement — Literal infringement (§120.05)

Determination that claims for patented bone growth stimulator device, as properly construed, encompass both skin anode and implanted anode warrants finding of literal infringement by defendant's device, in view of defendant's admission that literal infringement is avoided only if patented device's claims are construed to be limited to skin anode.

4. Patentability/Validity — Adequacy of disclosure (§115.12)

Patent infringement defendant which seeks to prove invalidity based upon nonenablement must show facts, supported by clear and convincing evidence, demonstrating that patent was not enabling, and federal district court findings that claims for patented bone growth stimulator device are not limited to specific metal/current combination, and that determination of optimal electrical current for materials other than stainless steel would require dose response study and would involve "undue amount of experimentation," are insufficient to establish clear and convincing proof of invalidity, since time and cost of such studies do not, standing alone, show experimentation to be excessive.

Particular patents — General and mechanical — Medical healing device

3,842,841, Brighton, Friedenberg, and Redka, constant current power pack for expediting healing of bone fracture and bone defects in living beings, including means of internal implant, and method of using device, valid and infringed.

Appeal from the U.S. District Court for the District of Colorado, Matsch, J; 3 USPQ2d 1571.

Patent infringement action brought by U.S. and Zimmer Inc., as involuntary plaintiff, against Telectronics Inc. and BGS Medical Inc. From federal district court's judgment holding that defendants did not infringe, that patent is not invalid under 35 USC 112, and holding that defendant Telectronics is not entitled to attorney's fees, parties cross-appeal. Affirmed in part and reversed in part.

John Fargo (Richard K. Willard, assistant attorney general and Vito J. DiPietro, with him on brief), Department of Justice, for plaintiff/appellant.

Michael I. Rackman, of Gottlieb, Rackman & Reisman, New York, N.Y. (Barry A. Cooper and Jeffrey M. Kaden, New York, and William C. Nealon, Suffield, Conn., with him on brief), for defendants/counterclaim-plaintiffs/cross-appellants.

Before Newman, Archer, and Mayer, circuit judges.

Archer, J.

The United States of America (government) appeals the judgment of the United States District Court for the District of Colorado in *United States v. Telectronics, Inc.*, 658 F.Supp. 579, 3 USPQ2d 1571 (D. Colo. 1987), holding that Telectronics, Inc. and BGS Medical, Inc. (Telectronics) do not infringe U.S. Patent No. 3,842,841 ('841). Telectronics cross-appeals the determinations that the '841 patent is not invalid under 35 U.S.C. §112 (1982) and that Telectronics is not entitled to attorney fees under 35 U.S.C. §285 (1982).[1] We reverse the district court's holding that the '841 patent is not infringed by Telectronics. The determinations that the patent is not invalid under section 112 and that Telectronics is not entitled to attorney fees are affirmed.

Background

The '841 patent issued to Carl T. Brighton, et al. and was assigned to the United States. The patent resulted from work under contract between the Office of Naval Research and the University of Pennsylvania, where the inventors were employed. 658 F.Supp. at 581, 3 USPQ2d at 1571. The '841 patent is directed to a bone growth stimulator device for speeding the healing of fractures and other bone defects. The accused devices of Telectronics are marketed under the name OSTEOSTIM and include Model 2000 and earlier models S-12, HS-12 and XM-12. Zimmer, Inc. (Zimmer), a licensee of the government under the '841 patent, also markets a bone growth stimulator which the district court found to be "quite similar to the preferred embodiment of the invention shown in the patent." 658 F.Supp. at 581, 3 USPQ2d at 1571.

Normally bone fractures heal naturally as a result of the body's own reparative process. Approximately five percent of the time, however, natural healing does not occur and bone grafting is conventionally employed to attempt to stimulate further reparative growth. 658 F.Supp. at 581-82, 3 USPQ2d at 1572.

Bone growth stimulators are particularly useful in the treatment of fractures normally requiring grafting. The success rate is at least as great as with grafting and the procedure results in less discomfort to the patient. 658 F.Supp. at 582, 3 USPQ2d at 1572. Bone growth stimulators expedite the healing of a fracture or bone defect by passing a low level constant direct current to the site of the fracture via a cathode placed internally at the site of the fracture. *Id.* The placement of the circuit-completing anode is at issue in this case.

The claim of the '841 patent at issue reads:

> 1. A system for expediting the healing of bone fractures and bone defects in a living being comprising:
>
> constant current source means for providing a constant value of current despite changes in load;
>
> means for connecting said constant current means to the living being, such connection acting to produce current flow into said fracture or defect,
>
> said connecting means including further means for application internally of said living being at the fracture or defect site,
>
> said constant current being a selected value within a predetermined microampere range so as to promote bone formation at the fracture or bone defect site and avoid fibrous tissue formation in other areas of the living being.

In describing the operation of the patented invention and the accused devices, the district court stated that

> [w]hen using the product of either party, the cathode (negative terminal) is placed in the defect site. The Zimmer cathode is made of stainless steel, the material described in the patent. The OSTEOSTIM cathode is made of titanium. The major

[1] Telectronics has not appealed the district court's holdings on other issues it raised below.

> difference between the products of the parties pertains to the anode (positive terminal). As disclosed in the patent drawing and accompanying description, and as marketed by Zimmer, the anode is placed on the skin of the patient. So is the power pack (current source) itself. The only internal element [in Zimmer] is the cathode — a pin which is inserted through the skin into the defect site. This technique avoids the need for surgery; after several months of treatment, the cathode pin is simply pulled out. The OSTEOSTIM device, on the other hand, is completely implanted, an embodiment which while not shown in the patent drawing is nevertheless described. The power pack and the anode of the OSTEOSTIM are placed in soft tissue near the bone. The original OSTEOSTIM S-12 had a power pack from which two wires extended, the wires terminating respectively at a titanium cathode for placement in the defect site, and a platinum anode for placement in the soft tissue. In all of the later models, including the OSTEOSTIM-2000, the anode wire was omitted. The anode is the case itself — titanium with a patch of platinum.

658 F.Supp. at 582, 3 USPQ2d at 1572.

Because the Telectronics devices have an implanted anode, the district court stated that "the critical question in the case is whether the language of claim 1 (and with it, the dependent claims) is limited to a skin anode." 658 F.Supp. at 583, 3 USPQ2d at 1573. Telectronics contended before the district court that "an internal anode could not come within the literal language of claim 1 because fibrous tissue formation inevitably results from such an implant." *Id.* In finding no literal infringement, the district court held with respect to the accused device that

> fibrous tissue formation could not be avoided in the dictionary sense of "keep away from" or "stay clear of".
>
> The claim limitation directed to the avoidance of fibrous tissue means what it plainly says. Accordingly, there is no literal infringement because in the context of the patent, even minimal fibrous tissue formation is not its avoidance. *Id.*

The district court also held that the '841 patent was not infringed under the doctrine of equivalents on the basis that the prosecution history established that the patentees, in responding to rejections by the examiner, repeatedly represented that the invention was limited to a surface or skin. anode. After examining the prosecution history in detail, the district court stated: "[i]t is clear from the file history that what convinced the Examiner to allow the claims over the prior art was the argument that a skin anode was used in the invention." 658 F.Supp. at 587, 3 USPQ2d at 1576.

On appeal, the government contends that the district court in its literal infringement analysis erred as a matter of law in its claim interpretation. According to the government, the claim limitation read as a whole requires the constant current supply to be controlled in a manner to minimize the amount of fibrous tissue formed. Telectronics counters that the district court properly interpreted the claim phrase "avoid fibrous tissue formation" and the prosecution history to find that the claim is limited to the use of a skin anode.

OPINION

1. *Claim Interpretation*

A. Analysis of literal infringement involves two inquiries: first the claims must be properly construed to determine their scope and then it must be determined whether the properly interpreted claims encompass the accused structure. *ZMI Corp. v. Cardiac Resuscitator Corp.*, 844 F.2d 1576, 1578, 6 USPQ2d 1557, 1559 (Fed. Cir. 1988). Claim construction is reviewed as a matter of law. However, interpretation of a claim may depend on evidentiary material about which there is a factual dispute, requiring resolution of factual issues as a basis for interpretation of the claim. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1054, 5 USPQ2d 1434, 1441 (Fed. Cir. 1988). In interpreting claims resort should be made to the claims at issue, the specification, and the prosecution history. *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 867, 228 USPQ 90, 93 (Fed. Cir. 1985). The question of literal infringement is a factual inquiry and is reviewed on a clearly erroneous standard. *Loctite Corp.*, 781 F.2d at 866, 228 USPQ at 93.

B. The district court interpreted the phrase "avoid fibrous tissue formation" as precluding the use of an implanted anode, and thus limiting the claim to a surface or skin anode. To the court, the word "avoid" based on its dictionary definition meant that there could be no fibrous tissue. Because an implanted anode inevitably resulted in some fibrous tissue, the court determined that this placement of the anode was not covered by the claim language.

The government argues that the district court erred in its interpretation because the phrase at issue was not read in context. It contends that the claim language read as a whole only requires that there be avoidance

or minimization of fibrous tissue formation by controlling or selecting the current. Thus, any fibrous tissue that may result from the implantation of the anode is immaterial.

[1] We agree that the district court erred in its interpretation of the limitation of claim 1 and in its conclusion that such language is determinative of the anode placement. In the claim, constant current is a "selected value . . . so as to promote bone formation . . . and avoid fibrous tissue formation in other areas." Nothing in this language relates to fibrous tissue that may be formed from implantation of an anode. The plain meaning of the disputed language is only that current related fibrous tissue formation is to be avoided.

In considering other sources for interpretation of claims, we note that the specification supports the plain meaning of the clause at issue. *See Autogiro Co. of America v. United States*, 384 F.2d 391, 397, 155 USPQ 697, 702-03 (Ct. Cl. 1967) ("[p]atent law allows the inventor to be his own lexicographer. . . . [t]he specification aids in ascertaining the scope and meaning of the language employed in the claims inasmuch as words must be used in the same way in both the claims and the specification.") The specification makes no mention of whether a skin anode or an implanted anode may cause or deter the formation of fibrous tissue. There is, however, a discussion of the increase or decrease in fibrous tissue that is formed with varying currents. Further, we find nothing in the prosecution history that would indicate that fibrous tissue resulting from implantation of an electrode was at issue or was intended to be covered by the claim language.

The claim language relied on by the district court is, therefore, not determinative of anode placement and does not require that claim 1 be limited to a surface or skin anode.

C. Claim 1 recites a "means for connecting said constant current means to the living being, such connection acting to produce current flow into said fracture or defect." Since this recitation is in the "means plus function" format permitted by 35 U.S.C. §112, ¶6, it must be interpreted to cover the structure disclosed in the specification and the equivalents thereof. *See D.M.I. Inc. v. Deere & Co.*, 755 F.2d 1570, 1575, 225 USPQ 236, 239 (Fed. Cir. 1985).

"In construing a 'means plus function' claim, as also other types of claims, a number of factors may be considered, including the language of the claim, the patent specification, the prosecution history of the patent, other claims in the patent, and expert testimony [citations omitted]. Once such factors are weighed, the scope of the 'means' claim may be determined." *Palumbo v. Don-Joy Co.*, 762 F.2d 969, 975, 226 USPQ 5, 8 (Fed. Cir. 1985); *see also Moeller v. Ionetics Inc.*, 794 F.2d 653, 656, 229 USPQ 992, 994 (Fed. Cir. 1986) (resort to extrinsic evidence, such as the prosecution history, is necessary to interpret disputed claims); *SSIH Equip. S.A. v. U.S. Int'l Trade Comm'n*, 718 F.2d 365, 376, 218 USPQ 678, 688 (Fed. Cir. 1983) (the prosecution history is always relevant to proper claim interpretation). "[T]he prosecution history (or file wrapper) limits the interpretation of claims so as to exclude any interpretation that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance." *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 452, 227 USPQ 293, 296 (Fed. Cir. 1985); *see also McGill Inc. v. John Zink Co.*, 736 F.2d 666, 673, 221 USPQ 944, 949 (Fed. Cir.), *cert. denied*, 469 U.S. 1037 (1984).

The district court found that both implanted and surface anodes are disclosed in the specification of the '841 patent. The specification provides: "[a]lthough the cathode must be placed in the fracture . . . the anode, though described as preferably being placed on the remote side of the site from the cathode, may be placed anywhere so long as it completes a circuit with the cathode." Elsewhere the specification provides that "[i]f the anode is to be implanted, it . . . is bared of its cover." Thus, unless other relevant claim interpretation factors clearly require a different construction, the plain language of claim 1 and the specification cover an implanted anode as well as a skin or surface anode.

In its claim construction and literal infringement analysis, the district court did not consider the prosecution history but concluded for the reasons indicated in I.A., *supra*, that a surface anode was required. The prosecution history, however, was extensively discussed in the court's consideration of the doctrine of equivalents.

Prior to allowance, the applicants communicated with the examiner six times. These communications are referred to as "A" through "F" in the district court's opinion and herein. The district court concluded that because of the prosecution history appellant is "prevented from construing its claims to include an internal anode." 658 F.Supp. at 587, 3 USPQ2d at 1577. We disagree.

The district court first relied on Amendments B and C. In the former, applicants inserted the limitation "only one of said connecting means applied to the skin surface of the living being" for the purpose of at-

tempting to overcome a prior art rejection. This amendment was accompanied by remarks to the same effect. In Amendment C, this limitation was argued to be a distinguishing feature of the invention. Applicants' attempts to distinguish over the prior art in this fashion were unsuccessful, and the claims were later amended to remove this recitation. The arguments emphasizing the use of a skin electrode, which were made at the time the application claims explicitly contained such a limitation, cannot furnish a basis for restricting issued claim 1, which lacks any such limitation. *See Smith v. Snow*, 294 U.S. 1, 16 (1935) ("It is of no moment that in the course of the proceedings in the Patent Office the rejection of narrow claims was followed by the allowance of the broader Claim 1."); *Kistler Instrumente AG v. United States*, 628 F.2d 1303, 1308, 211 USPQ 920 (Ct. Cl. 1980) (*aff'g* and adopting 203 USPQ 511, 516) (courts are not permitted to read "back into the claims limitations which were originally there and were removed during prosecution of the application through the Patent Office.")

In Amendment D a claim which ultimately issued as independent claim 1 was submitted for the first time. In holding claim 1 should be limited to a skin anode, the district court relied on Amendments E and F which contained arguments relative to a skin anode and which were held by the district court to be in support of the claims that finally issued.[2] From Amendment F the district court quoted the following language:

> Applicants take strong exception to [the examiner's] analysis of the [Friedenberg-Kohanim article]. Nowhere in this article is there either stated or suggested that one of the electrodes need simply be applied to the surface and the other introduced into the fracture site.

These remarks were submitted to correct the examiner's characterization of a prior art reference (an article written by one of the co-inventors of the patented invention). The examiner's characterization of the reference was made in rejecting claims, at least some of which included an explicit recitation of a surface anode. Thus, these remarks are of little significance.

The district court also noted the following argument in Amendment F:

> Applicants throughout the prosecution of this case have repeatedly attempted to convey to the Examiner the important differences between their technique where only one of the electrodes need pierce the skin *and enter the fracture site* and the other prior art arrangements where two electrodes have to pierce the skin *and then fit into prescribed locations formed in the bone structure* under study. (Emphasis added.)

The quoted language does not mean that one electrode must remain on the surface of the skin. Rather, as applicants argue, it means that both of their electrodes do not have to be placed in the bone structure itself. The district court erred in construing the phrase "only one of the electrodes need pierce the skin" to mean that the other electrode must remain on the surface. This phrase, when read in conjunction with the words that follow — "and enter the fracture site" — only serves to distinguish prior art where both electrodes were placed in the bone structure.[3] The entire emphasis of the prior art article was that the electrodes were placed in the bone for the purpose of attempting to lengthen the bone. The article was not concerned with the healing of fractures or bone defects. In the healing of fractures, it is not necessary (or desirable) to place both electrodes in the bone.

[2] D. "There is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims. To the extent that the absence of such difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between claims is significant." *Tandon Corp. v. United States Int'l Trade Comm'n*, 831 F.2d 1017, 1023, 4 USPQ2d 1283, 1288 (Fed. Cir. 1987). "Where some claims are broad and others narrow, the narrow claim limitations cannot be read into the broad whether to avoid invalidity or to escape infringement. *Uniroyal, Inc.*, 837 F.2d at 1054-55, 5 USPQ2d at 1441 (quoting *D.M.I., Inc. v. Deere & Co.*, 755 F.2d at 1574, 225 USPQ at 239).

In this case the district court erroneously construed claim 1 so that its limitations are

[2] There was some uncertainty as to which set of claims certain of these remarks applied, but the district court found that Amendments E and F related to the claims presented in Amendment D. Because we conclude that the district court erroneously limited the claims even if the remarks in controversy did apply to the claims which issued, we need not determine whether the district court correctly resolved this dispute.

[3] The district court recognized that "[t]here are three possible positions for placement of the anode: on the skin, in soft tissue, and in the bone. Placement within the bone must be done carefully to avoid the effect of insulation from the cortical bone." 658 F.Supp. at 583, 3 USPQ2d at 1573.

the same as dependent claim 2. Claim 2 reads in its entirety: "The system as defined in claim 1 wherein said connecting means includes means for external application to the skin surface, the internal means being a cathodic electrode, the external means being an anodic electrode." The doctrine of claim differentiation, therefore, counsels against limiting claim 1 to the use of a skin anode. *See D.M.I., Inc.*, 755 F.2d at 1574, 225 USPQ at 239.

E. On the basis of the above analysis, we conclude that the district court erred as a matter of law in its interpretation of claim 1 of the '841 patent. *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1569, 219 USPQ 1137, 1140 (Fed. Cir. 1983).

The ordinary and accustomed meaning of claim 1 is that the current should be applied so as to avoid the formation of fibrous tissue. In support of this means plus function claim, the specification of the '841 patent disclosed both an implanted and a surface anode structure. The other claims, the specification and the prosecution history do not require a narrower construction. Thus, the district court erred in limiting claim 1 to the use of a skin anode.

II. *Literal Infringement*

The question of literal infringement is a factual inquiry. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d at 1054, 5 USPQ2d at 1441. Literal infringement requires that every limitation of the patent claim must be found in the accused device. *Mannesmann Demag Corp. v. Engineered Metal Prods. Co.*, 793 F.2d 1279, 1282, 230 USPQ 45, 46 (Fed. Cir. 1986). In this case, the findings of the district court establish literal infringement and, thus, there is no need to remand for a determination of the factual question of infringement under properly interpreted claims.

[3] The district court stated in its opinion that:

> The defendant's denial of infringement in this case is based solely on the defendants' anode and case being used internally. Accordingly the critical question in the case is whether the language of claim 1 (and with it the dependent claims) is limited to a skin anode.

As we have held in I., *supra*, the properly construed claims encompass both a skin anode and an implanted anode. The district court erroneously limited the claims of the '841 patent to a surface anode. Accordingly, on the position of Telectronics as stated by the district court, literal infringement is established.

The government also challenges the district court's finding of no infringement under the doctrine of equivalents. Because the accused devices literally infringe, a doctrine of equivalents inquiry is unnecessary. *See ZMI Corp. v. Cardiac Resuscitator Corp.*, 844 F.2d at 1581, 6 USPQ2d at 1562 ("When literal infringement is not found, the equitable doctrine of equivalents comes into play.").

III. *Invalidity*

The district court held: "[i]f claim 1 were to be given the broad meaning which plaintiff asserts, then the patent would be invalid for a failure to comply with the specification requirements of 35 U.S.C. §112." 658 F.Supp. at 589, 3 USPQ2d at 1577-78. According to the district court a dose response study must be performed for materials other than stainless steel to determine the optimal electrical current to be supplied and this would involve "an undue amount of experimentation." *Id.*

In its cross-appeal Telectronics argues that the patent is invalid for non-enablement regardless of how the claims are interpreted because the disclosure does not bear a reasonable relationship to the scope of the claims.

Enablement is a legal determination which is reviewed as a matter of law. *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 951-60, 220 USPQ 592, 599 (Fed. Cir. 1983). To be enabling under section 112, the patent must contain a description sufficient to enable one skilled in the art to make and use the claimed invention. *Id.* A patent may be enabling even though some experimentation is necessary; the amount of experimentation, however, must not be unduly extensive. *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984). A patent is presumed valid, and the burden of proving invalidity, whether under section 112 or otherwise, rests with the challenger. Invalidity must be proven by facts supported by clear and convincing evidence. *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1573-74, 227 USPQ 177, 178 (Fed. Cir. 1985) ("A party asserting invalidity based on 35 U.S.C. §112 bears no less a burden . . . than any other patent challenger.") Thus, although not mentioned by the district court it is Telectronics' burden to show by facts supported by clear' and convincing evidence that the patent was not enabling.

We note first that Telectronics admits that "[t]he patent *does* disclose how to successfully practice the invention — if stainless

steel electrodes and a current in the range of 5–20 microamperes is [sic] used." (Emphasis in original.) Lack of enablement is asserted on the basis that "the claims are not limited to the specific metal/current combination."

The district court thought that to determine the optimal electrical current for materials other than stainless steel a dose response study would be required and that this would involve an "undue amount of experimentation." The district court said "the patent does not tell a person reasonably skilled in the art how to make and use this invention because it fails to teach how to select a level of current to promote bone formation and avoid fibrous tissue . . . formation from such current" for electrodes made of materials other than stainless steel. 658 F.Supp. at 589, 3 USPQ2d at 1578. It noted that "the patent does not contain an adequate description of the methodology for a dose response study for any cathode material other than stainless steel" and that "only those who were expert in the field and actually working with bone, doing electrical stimulation experiments . . . would know how to conduct" such a study. Moreover, the district court thought that the time and expense of such a study also indicated undue experimentation would be required.

[4] We are convinced that these findings and conclusions are insufficient to constitute clear and convincing proof of invalidity. First, it is undisputed that the patent disclosures are enabling with respect to stainless steel electrodes, with the range of current for such electrode set out in the specification. The specification shows this range of current was obtained by a dose response test. Next, according to the district court "those who were expert in the field and actually working with bone, doing electrical stimulation experiments . . . would know how to conduct a dose response study to determine the appropriate current to be used with other materials as electrodes." *Id.* The appropriate levels of current for other electrodes to promote bone growth and avoid fibrous tissue could, therefore, be determined. Finally, the emphasis by the district court on the time and cost of such studies is misplaced. While these factors may be taken into account, in the circumstances of this case we are unpersuaded that standing alone they show the experimentation to be excessive. The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 107 S.Ct. 1606 (1987).

Since one embodiment is admittedly disclosed in the specification, along with the general manner in which its current range was ascertained, we are convinced that other permutations of the invention could be practiced by those skilled in the art without undue experimentation. *See SRI Int'l v. Matsushita Elec. Corp. of America*, 775 F.2d 1107, 1121, 227 USPQ 577, 586 (Fed. Cir. 1985) (the law does not require an applicant to describe in his specification every conceivable embodiment of the invention); *Hybritech Inc.*, 802 F.2d at 1384, 231 USPQ at 94 (the enablement requirement may be satisfied even though some experimentation is required). While perhaps fortuitous, as the district court found, the OSTEOSTIM device of Telectronics used a current level of 20 microamperes, within the "substantially 5 microamperes to substantially 20 microamperes" range set forth in claim 5 and disclosed in the specification.

The district court also held that if claim 1 is read to mean that the current must be applied so as to minimize fibrous tissue formation then it would be invalid under 35 U.S.C. §112 (1982) because it would be "impossible to determine when sufficient minimization takes place to determine what current range is involved." 658 F.Supp. at 589, 3 USPQ2d at 1578. The district court erred as a matter of law in this holding. *Shatterproof Glass Corp. v. Libby-Owens Ford Co.*, 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir.), *cert. dismissed*, 106 S.Ct. 340 (1985). Section 112, ¶2, requires only reasonable precision in delineating the bounds of the claimed invention. *Id.* Adjusting current so as to minimize fibrous tissue formation in other parts of the living being reasonably apprises those skilled in the art of the bounds of the claimed invention and is as precise as the subject matter permits. *See id.* Thus, we hold as a matter of law that the '841 patent is enabling and that the claims satisfy 35 U.S.C. §112, ¶2.

In its cross appeal, Telectronics argues that the specification is enabling only for the use of stainless steel while the claims are not limited in the types of material from which the electrodes can be made. It contends that the scope of the protection must bear a reasonable relationship to the scope of enablement, citing *In re Fisher*, 427 F.2d 833, 838–39, 166 USPQ 18, 23–24 (CCPA 1970) ("In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved."),

and *In re Bowen*, 492 F.2d 859, 861-64, 181 USPQ 48, 50-52 (CCPA 1974) (section 112 requires that the scope of claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art). *Fisher* and *Bowen* both involved chemical reactions, recognized by our predecessor court as having a high degree of unpredictability and therefore requiring an increased enablement disclosure. Yet, in *Bowen* the board's non-enablement rejection was reversed where the "claims literally comprehend numerous polymers in addition to the one specifically described in appellant's specification" because no persuasive reason was given by the Patent Office why the specification does not realistically enable one skilled in the art to practice the invention as broadly as it is claimed. *In re Bowen*, 492 F.2d at 863, 181 USPQ at 51-52. The same can be said here. The only impediments are the time and cost of a dose response study, which the district court found could be performed by "those who were expert in the field and actually working with bone, doing electrical stimulation experiments . . . , " i.e., those skilled in the art. Moreover, as we have noted, Telectronic's device using different electrode materials actually operated within the current parameters disclosed in the specification.

We conclude that the district court erred in its nonenablement conclusion and that facts supported by clear and convincing evidence of invalidity were not adduced.

In view of our decision, we need not consider the district court's denial of attorney fees to Telectronics.

Costs

The parties shall bear their respective costs.

AFFIRMED-IN-PART AND REVERSED-IN-PART

Court of Appeals, Sixth Circuit

Robert R. Jones Associates Inc. v. Nino Homes

No. 87-1494

Decided September 20, 1988

COPYRIGHTS

1. Rights in copyright; infringement — Right to reproduction in copies or phonorec rds — Access, copying and substantial similarity (§213.0503)

Evidence, in copyright infringement action against home builder for unauthorized copying of architectural drawings, demonstrating that photocopy of drawings was found in files of architectural firm that designed defendant's allegedly infringing plans, together with defendant's admission that he made copies of infringing plans, and together with finding that defendant's plan is substantially similar to plaintiff's is sufficient to demonstrate defendant's access and to warrant finding that defendant has infringed.

2. Rights in copyright; infringement — Right to reproduction in copies or phonorecords — In general (§213.0501)

Home builder may, without violating Copyright Act, construct house which is identical to house depicted in copyrighted architectural plans, but may not directly copy those plans and then use infringing copy to construct house.

3. Infringement pleading and practice — Relief and damages — Statutory damages and profits (§217.1103)

Damages recoverable for home builder's direct copying of architectural plans include plaintiff's losses resulting from defendant's subsequent use of infringing copies, and federal district court therefore properly awarded plaintiff profits it would have earned but for defendants' sale of seven houses built from infringing plans, but court's addition to award of defendant's profits constitutes double recovery prohibited by 17 USC 504(b), since defendant's profit per house was less than plaintiff's profit margin and since all of defendant's sales were counted as sales lost by plaintiff.

4. Infringement pleading and practice — Relief and damages — Costs and attorney's fees (§217.1105)

Award of attorney's fees against defendant home builder who copied plaintiff's architectural plans and then constructed homes based on those plans is barred by 17 USC 412(2), which prohibits award of fees for infringements that occur after publication but before copyright registration, since plaintiff's registration took effect in 1983, and since defendant's infringing act, which consisted of its copying of plans, took place after plans' first publication but before registration became effective.

REMEDIES

5. Monetary — Damages — Prejudgment interest (§510.0511)

Federal district court's award of prejudgment interest for defendants' infringement of